

as "Attachment #2"), showing the "Rhodiola" spelling. Consequently, applicants have amended the specification, specifically page 6, line 32, to include both spellings of the word. However, in the interest of furthering the prosecution of this application, applicants have amended aforementioned claims 1, 11 to 13, and 16 to reflect the "Rhodiola" spelling.

The Office Action has rejected claims 6 to 9, 11, 12, and 16 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. More specifically, the Office Action sets forth that these claims are considered indefinite because claim 1 states that *Azadiracta* is a required ingredient in the composition (line 11); however, claims 6 to 9, 11, 12, and 16 do not include *Azadiracta* in the composition. In response, applicants submit that claim 1 only requires that the composition include at least one of either *Gynostemma*, coconut water, *Azadiracta*, or *Rhodeola*. *Azadiracta* is one of four possible plant ingredients that may be required either alone or in combination with one or more of the others. However, when the plant ingredient is from *Azadiracta* seed, claim 1 requires that the composition further includes at least one other ingredient selected from the group consisting of *Gynostemma*, coconut water and *Rhodeola*. That is, claim 1 only requires that the composition also include at least one of either *Gynostemma*, coconut water or *Rhodeola*, whenever *Azadiracta* is present (the absolute presence of which is not a requirement of the claim). Applicants submit that claims 6 to 9, 11, 12, and 16 clearly point out and distinctly claim the subject matter that applicants regard as the invention.

The Office Action has rejected claims 1 to 9, and 11 to 16 under 35 U.S.C. §103(a) as being unpatentable over GB '971, JP '414, RU '119, and the Sabinsa Corporation webpage. Claims 1 and 10 are rejected under 35 U.S.C. §103(a) as being unpatentable over GB '971, JP '414, RU '119, and the Sabinsa webpage as applied to claims 1 to 9 and 11 to 16 above, and further in view of US '423. Claims 1 to 9 and 11 to 16 are rejected under 35 U.S.C. §103(a) as being unpatentable over GB '971, JP '414, RU '119, and DE '109. Claims 1 and 10 are rejected under 35 U.S.C. §103(a) as being unpatentable over GB '971, JP '414, RU '119, and DE '109 as applied to claims 1 to 9 and 11 to 16 above, and further in view of US '423.

Claim 1 has been amended to include, in part, at least one plant ingredient selected from the group consisting of *Gynostemma*, coconut water, *Azadiracta*, and *Rhodiola* present in an amount effective to improve the aesthetic appearance of skin; and a pharmaceutically or cosmetically acceptable vehicle, wherein when the plant ingredient is from *Azadiracta* seed, the composition further includes at least one other ingredient selected from the group consisting of *Gynostemma*, coconut water and *Rhodiola*.

Applicants submit that GB '971, JP '414, RU '119, DE '109, and the Sabinsa Corporation webpage, some of which are only abstracts, are all directed specifically to hair care compositions. As set forth in the Office Action, GB '971 teaches a hair treatment formulation that uses *Azadiracta* (neem) seed extract to treat dandruff and balding. JP '414 teaches a hair composition that uses *Gynostemma* to treat dandruff and alopecia. RU '119 teaches a hair shampoo that uses *Rhodiola* to improve hair and prevent hair loss. The DE '109 abstract has

been cited by the Examiner for teaching the use of coconut milk to prevent hair loss. The Sabinsa webpage has been cited for teaching the use of coconut water in hair care formulations. The Examiner has also cited US '423 for teaching neem seed culture to create a pharmaceutical extract.

Applicants respectfully submit that the references cited by the Examiner, taken alone or in any cited combination, neither disclose nor suggest the claims of the present invention. Unlike the aforementioned cited references, and as set forth above, independent claim 1 covers, in part, a skin composition having at least one plant ingredient selected from the group consisting of *Gynostemma*, coconut water, *Azadiracta*, and *Rhodiola* present in an amount effective to improve the aesthetic appearance of skin. In contrast to claim 1, there is nothing in the references cited by the Examiner that teaches or suggests that the disclosed plant ingredients are present in an amount effective to improve aesthetic skin appearance. Instead, all of the references specifically teach hair care formulations. Furthermore, as conceded by the Examiner, the references also do not teach adding the ingredients in the amounts claimed by applicants.

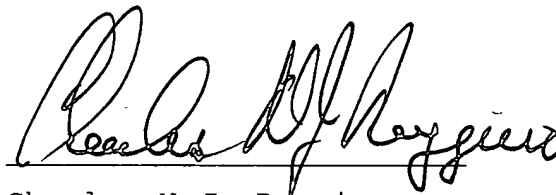
As set forth above, the Office Action also cites to US '423 merely for teaching using a neem seed culture to create a pharmaceutical extract, as the rest of the references do not specifically teach using a neem seed culture in the composition. However, in contrast to US '423, claim 1 requires a second plant ingredient when the first ingredient is from *Azadiracta* seed. As such, and also for the reasons set forth above, claim 1 is patentably distinguishable.

Applicants submit that claim 1, as amended, obviates the §103(a) rejections set forth in the Office Action. Furthermore, claims 2 to 16 depend from claim 1. Thus, they are also patentably distinguishable for at least the same reasons as discussed above with respect to claim 1. As such, the §103(a) rejections should be withdrawn. Also, the compositions of claims 1 to 16 are clearly in condition for immediate allowance.

In view of the foregoing, Applicants respectfully submit that the claims of the present invention are allowable, request that all rejections be reconsidered and withdrawn, and that the claims of this application be given favorable consideration and passage to allowance.

February 5, 2003

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Charles N.J. Ruggiero", written over a horizontal line.

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VERSION WITH MARKINGS TO SHOW CHANGES MADEIn the Specification:

The paragraph beginning at page 6, line 30 has been amended as follows:

The plant ingredients preferably include the following:

*Gynostemma*; coconut water; *Azadirachta* (neem including its cell cultures, broth and/or extracts); and *Rhodeola* (also spelled "Rhodiola"). Especially preferred blends of plant ingredients are *Azadirachta* and one or more other ingredient, particularly *Gynostemma*, coconut water and/or *Rhodeola*. The amount of the active botanical ingredient(s) in the compositions of the present invention is about 0.0001 percentage by weight or weight percent (wt%) to about 50 wt%, preferably about 0.001 wt% to about 10 wt%, more preferably about 0.01 wt% to about 5 wt%, and still more preferably about 0.1 wt% to about 3 wt%, of the total weight of the composition.

In the Claims:

1. (Amended) A [topical] skin composition, comprising:

at least one plant ingredient selected from the group consisting of *Gynostemma*, coconut water, *Azadiracta*, and [*Rhodeola*] *Rhodiola* present in an amount effective to improve the aesthetic appearance of skin; and

a pharmaceutically or cosmetically acceptable vehicle, wherein when the plant ingredient is from *Azadiracta* seed, the composition further includes at least one other ingredient selected from the group consisting of *Gynostemma*, coconut water and [*Rhodeola*] *Rhodiola*.

11. (Amended) The composition of claim 1, wherein the at least one plant ingredient is [*Rhodeola*] *Rhodiola*.

12. (Amended) The composition of claim 11, wherein [*Rhodeola*] *Rhodiola* is present in an amount about 0.001 wt% to about 10 wt% of the total weight of the composition.

13. (Amended) The composition of claim 1, wherein said plant ingredients are *Gynostemma*, coconut water, *Azadirachta* and [*Rhodeola*] *Rhodiola*.

16. (Amended) The composition of claim 1, wherein the plant ingredient is selected from the group consisting of *Gynostemma*, coconut water, and [*Rhodeola*] *Rhodiola*.



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#### *Ginseng*

The ability of all species of ginseng to increase virility and stimulate sexual activity is a concept that is ingrained in Traditional Chinese and Korea, Medicine.<sup>3,4,17,19</sup> Several studies in animals and uncontrolled observations in humans confirm the ability of ginseng various types to stimulate sexual activity.<sup>13</sup> Ginseng is an expensive herb because the plant is slow to mature and requires intensive cultivation.

There is a criticism that double-blind controlled trials of ginseng's ability to stimulate sexual activity are lacking.<sup>1</sup> However, evidence exists that types of ginseng can increase sperm formation, increase testosterone levels, and enhance sexual activity in several animal species.<sup>8,9,12</sup> Ginseng has been reported even to stimulate egg laying in hens.<sup>8</sup> Dr. Murray and Joseph E. Pizzomo, Jr., N.D., in their book, *Encyclopedia of Natural Medicine*, Second Edition,<sup>20</sup> conclude that the results of experiments with ginseng support the use of this herb as a fertility and virility enhancer.<sup>20</sup>

There is no consensus on the best type of ginseng for enhancing sexual function (American, Korean, Siberian, or Chinese). Leading authorities on the subject of ginseng such as Stephen Fulder, Ph.D., author of *The Book of Ginseng*, provide little guidance about appropriate doses.<sup>21</sup> For use alone as a stimulant for sex, an average dose of 500-1000 mg of capsules standardized for 5-9 percent ginsenoside is used.

#### *Niacin Improves Blood Circulation*

Niacin is a B-complex vitamin (vitamin 33) that has been used in the treatment of high blood cholesterol poor circulation caused by arteriosclerosis, and some psychiatric disorders.<sup>3,22</sup> There is a widespread and somewhat inappropriate perception that niacin is toxic. However, toxicity from niacin is only encountered at high doses, such as those required to treat high blood cholesterol.<sup>22</sup> A full therapeutic dose of crystalline niacin to lower cholesterol effectively is quite high and may be as much up as to 3 g per day.<sup>22</sup> At these high doses flushing, liver problems, and gastric upset are common. High doses of niacin used in treatment must be monitored by a physician. Flushing is caused by dilation (enlargement) of blood vessels. A small amount of niacin is a good way of causing a gentle stimulation to the circulation.

#### *Enhancing Sex for Females*

Sexual dysfunction is shared by females, but their problems are often quite different from males in both physical and psychologic contexts.<sup>1</sup> The behavior of the male during sex is directed ideally to the needs of the woman. There are many causes of sexual dysfunction in females, ranging from psychologic issues to problems that border on both the organic and psychologic, such as dyspareunia, frigidity, menstrual problems, and poor adaptation to the menopause. It is beyond the scope of this article to address all of these issues in detail.<sup>1</sup> There are a number of natural agents that can be combined to assist women in their promotion of better sexual intercourse. However, it must be understood that male impotence has dominated scientific searches for sexual stimulants.<sup>1</sup>

#### *Passion Flower*

Passion flower (*Passiflora incarnate*) extracts have had most use as a minor tranquilizer, and they have been used extensively in folklore medicine as a female tonic.<sup>8,23</sup> Preparations of passion flower are made from the flowers, leaves

and fruit of the creeping vine. The real use of passion flower is as an adaptogen.<sup>13</sup> Passion flower can be used in females to calm the mind when it is disturbed by repeated hormonal adjustments that occur in women.<sup>8,13</sup>

Passion flower cannot be considered to be an aphrodisiac per se, but this herb is recognized as being an effective remedy for "nerves" that are "on edge."<sup>8</sup> Lutomski has drawn attention to the "balance" brought to females by passion flower in his paper, "Die Bedeutung der Passionsblume in der Heilkunde" ("The Meaning of Passion Flower in Medical Science").<sup>23</sup> The tranquilizing benefits of passion flower are particularly useful in nervous manifestations of menstrual problems, menopause, and sexual activity.<sup>4,8,23</sup>

An average dose of passion flower in a solid, natural form is approximately 500 mg. There are no known side effects or contraindications for passion flower, according to Dr. Tyler in his book, *The Honest Herbal*.<sup>13</sup>

#### *Black Cohosh*

Black cohosh (*Cimicifuga racemosa*) is a native, North American Native American remedy that is used primarily for diseases of women and has special effects on female genitalia and the reproductive tract.<sup>24</sup> The herbal extract is derived from the rhizome and roots of *Cimicifuga racemosa*, a North American plant that is sometimes called squaw root, black snakeroot, rattleroot, or bugwort.<sup>13,24</sup> These names are confusing and any female patient who is interested using black cohosh should be told to make sure that the extract is from *Cimicifuga racemosa*.<sup>12,24</sup>

Black cohosh is believed to promote healthy menstrual activity and is believed by many herbalists to be capable of "soothing" the female sexual organs, in particular, by reducing unwanted congestion of the vagina, cervix, and uterus.<sup>24</sup> Several sources refer to the ability of black cohosh to produce both anti-inflammatory and contractile activity in the uterus.<sup>24</sup> Animal experiments indicate that fractions of black cohosh can bind to estrogen hormone receptors in the uterus.<sup>24</sup> Black cohosh is reported to cause a reduction in luteinizing hormone (LH) levels in rats that have had their ovaries removed. LH is secreted by the pituitary gland and it plays a role in regulating menstruation.<sup>24</sup> Overall, black cohosh is believed to have weak estrogenic actions.<sup>1,24</sup>

Black cohosh has become popular as a component of herbal remedies for menopausal well-being and is believed to assist in suppressing unpleasant symptoms of menopause, such as hot flashes.<sup>24</sup> The beneficial actions of black cohosh on the tissues of the female reproductive tract<sup>24</sup> and the herb's ability to soothe nervous tension combine to make it an ideal ingredient to contribute to sexual experiences in women.

#### *Wild Yam*

Ayurvedic medicine reveres wild yam (*Dioscorea villosa*) as a remedy for impotence and for infertility in females.<sup>8</sup> Mexican wild yam contains various saponin compounds that may have been converted, in laboratory experiments, into sex hormones, including testosterone and progesterone.<sup>13</sup> It is proposed that wild yam can be used by both males and females to enhance the production of sex steroids in the liver.<sup>8,13</sup> ; doubt exists.

It is reported that Mexican wild yam can help to balance the ratio of the levels of progesterone to estrogen in the body.<sup>13</sup> This may tend to alleviate symptoms of premenstrual tension and menopausal symptoms. Wild yam appears to be safe and nontoxic.<sup>13</sup>

#### *Damiana*

Damiana (*Tumera diffusa*) is a popular Mexican aphrodisiac that contains an oil that is stimulating to the urinary tract.<sup>8,9</sup> This herb is believed to be able to increase the sensitivity of the clitoris and penis. Certainly, an enhanced sensitivity of the clitoris will favor the occurrence of "clitorine" types of orgasm during sex and the herb has been successfully used for this purpose.<sup>1</sup>

Damiana is used mainly as a sexual stimulant in females but it is being used increasingly by men also.<sup>8,9</sup> Unfortunately, the heightened sensitivity of the penis produced by Damiana can lead to premature ejaculation in some males. This may be a reason to avoid it in male herbal formulas that are used to stimulate sex. Controlled clinical trials of the use of Damiana as a sexual aid have not been performed but this herb has had powerful endorsements from satisfied users.

#### *Chasteberry*

Despite its name, chasteberry (*Vitex agnus-castus*) is a favorite herb in Europe that is used for its beneficial effects on the female genitalia, the reproductive tract, and sexual desire.<sup>8,9,13</sup> This herb is derived from the fruit of the shrub, *Vitex agnus-castus*.<sup>9</sup> *Vitex* is sometimes called chaste tree.<sup>13</sup> It was once thought that vitex promoted chastity by decreasing sexual drive, and several centuries ago, the herb was used in syrup form to be taken by priests and nuns who wished to maintain celibacy.



Chaste tree may not provoke sexual desire but it may act to alter hormonal status in women (and perhaps in men). By this hypothesized mechanism, the herb may facilitate healthy sexual function.<sup>8,9</sup> Vitex has been shown to affect the secretion of pituitary hormones and of particular interest is its ability to reduce prolactin levels.<sup>8</sup> High circulating levels of prolactin in the blood occur during stress and have been associated with diminished sexual function in both males and females. Excessive prolactin secretion occurs with some drugs, e.g., metoclopramide, that can contribute to male impotence. The use of vitex may stimulate the pituitary gland to secrete LH, which may lead to increased levels of progesterone; this could account for vitex's reported ability to treat premenstrual syndrome (PMS), excessive or "heavy" periods, and uterine fibroid growths.<sup>8</sup>

#### *Dong Quai*

Dong quai is produced from the root of the Chinese plant *Angelica sinensis*.<sup>12</sup> Dong quai is sometimes called tang kuei and dang qui, and it is used most frequently in modern herbal medicine for the treatment of many gynecologic disorders.<sup>17</sup> Many of the common applications of dong quai are similar to the uses of *Angelica*.<sup>13</sup> *Angelica* is an herb that is used often in American and European herbology as a kind of substitute for dong quai.<sup>13</sup> However, *Angelica* (American and European) has some significant differences from dong quai, including *Angelica*'s origin from various parts of a different plant, *Angelica archangelica*.<sup>13</sup> One common use of *Angelica* is in the flavoring of alcoholic beverages, such as gin and liqueurs.<sup>9,13</sup>

Dong quai has been used extensively in Traditional Chinese Medicine for the treatment of menstrual cramps, abnormal menstruation, and PMS.<sup>17</sup> One of the herb's major uses has been in the management of menopause for which the herb is described as assisting in suppressing unpleasant symptoms that occur at the time of cessation of menstruation.<sup>9</sup> In herbal practice dong quai is said to be a general maintainer of gynecologic health and a balancer of "vital energy".<sup>17</sup> Some sources report dong quai to be an effective antispasmodic and it has been used for general "purification" of the body.<sup>17</sup> The use of dong quai as a body "purifier" is accepted in Traditional Chinese Medicine, but not in conventional Western medicine.<sup>17</sup>

The active ingredients of dong quai are not well defined but it contains number of compounds that resemble drugs called coumarins.<sup>8,9,13,17</sup> The compounds include psoralen, imperatorin, and oxypeucedanin. It is recognized that these coumarin-type compounds can cause vasodilation. This can lower blood pressure, relax smooth muscle, and even stimulate the central nervous system.<sup>9,13</sup>

Dong quai has recently been used as a "female tonic" in North America and Western Europe. It is believed that this herb can stimulate estrogen secretion and perhaps contribute to red blood cell production.<sup>17</sup> One concern has surfaced was the use of larger doses of dong quai. That is the problem of photosensitization, in which an individual can react adversely to exposure to sunlight. This is related to the content of psoralens, but it is not a common problem and can be avoided mostly by the use of dong quai in intermittent small doses. It should be noted that photosensitivity can occur with several prescription drugs including the commonly used antibiotic, tetracycline. Dong quai seems to be a useful agent in female herbal products for promoting general and genital health.

#### *Soy Isoflavones*

The principal soy isoflavones, genistein and daidzein, have versatile and potent effects on general health.<sup>25,26</sup> These components of soy have been proposed as a viable alternative to standard estrogen replacement therapy.<sup>26</sup> They can reduce unpleasant symptoms that occur during menopause and may help to relieve symptoms of PMS.<sup>26</sup> The weak estrogenic effects of genistein and daidzein may contribute to the reversal of vaginal dryness<sup>25,26</sup> in menopausal females, and the ascribed health benefits of soy for a female make these isoflavones candidates for inclusion in a sex-enhancing, dietary supplement formula.

#### *Other Agents*

It is not possible to review all herbals and botanicals that are used as sexual stimulants. Arctic root (*Rhodiola rosea*) has become popular, but evidence for its efficacy is lacking. Green oats and high doses of amino acids (e.g., L-arginine) to promote nitric oxide production are of questionable benefit.

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Rhodiola rosea also called Arctic root or Golden root a highly prized herb from the polar arctic region is ready to make its mark on the new world. Emperors of China used to organize expeditions to Siberia to bring back this highly valued plant. In Siberia it's said, "people who take rhodiola will live beyond 100 years."

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In a study of 128 individuals of all ages with various forms of depression who were given Rhodiola rosea, the main ingredient in Lift™ all test subjects showed positive therapeutic effects. And, 65% had complete disappearance of their depression. It is thought to work by making serotonin's precursors, tryptophan and 5-HTP, more available to the brain and by increasing the amount of serotonin in the brain (needed by people on low carb diets). In a separate placebo controlled study involving 130 overweight patients over 90 days at the Georgian State Hospital (in the former Soviet Union), of those who consumed rhadiola rosea, 92% lost a remarkable average of 20 pounds while a placebo group on the same diet lost just 7 pounds. This difference is presumably due to Lift™'s ability to activate adipose lipase, a key enzyme required to burn the body's fat stores. Other benefits of this amazing herb include it's **ability to:**

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- Increase body's ability to handle stresses of all kinds. Partly by calming the sympathetic (fight or flight) nervous system and relaxing the parasympathetic system. Subjects given the chief ingredient in Lift™ showed increased levels of beta-endorphin (the stress relieving, feel-